SICOBIO
Consolidation and Analysis System of Biomedical Information

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Abstract: Improving information systems and guaranteeing the quality of health services are current challenges for global governments. Financing problems and congestion in health care centers, increased demand for services due to aging population, mobility issues and insecurity, risks of accidents and contagion of diseases in care centers are some of the problems to be solved. In order to reduce these problems, it is necessary to take advantage of technological advances to give alternative solutions. This paper presents SICOBIO, a system for monitoring patients who finish their treatment at home, and facilitates the integration of devices and analysis algorithms. The information from remote sensors is homogenized, consolidated, and analyzed in a synchronous and asynchronous manner. Through synchronous analysis, the patient's risk is assessed and alerts are generated to his caregivers, and through asynchronous analysis, decision-making is supported with statistical and data mining techniques applied to historical information. SICOBIO was validated with devices for remote monitoring of physical activity, heart rate and weight. It demonstrated its scalability to incorporate new equipment and new algorithms of analysis and delivery of alerts. Its potential utility was validated through the Technology Acceptance Model (TAM).

1 INTRODUCTION

Improving information systems (Tovar-Cuevas and Arrivillaga-Quintero, 2014), and guaranteeing access to health care services for citizens in conditions of equality and quality, are some of the current challenges (Scheil-Adlung, 2013). The increase in life expectancy (Celler and Sparks, 2015), employment informality, and the low percentage of contributors to the funds that support the health care services, compromise the sustainability of the system (Zapata Jaramillo and Sánchez Villavicencio, 2012). With the increase in life expectancy, the demand for health services for the elderly is increased, who must assume travel costs, insecure situations, risks of falls, long travel times, long waiting times, and the risk of contagion of diseases in health care centers (Morelos Ramírez et al., 2014). These conditions that generate higher costs to the system, can be avoided if the patient is prevented from moving to the care centers or if the patient is able to complete his recovery at home, as long as he is guaranteed adequate follow-up (González et al., 2012).

Previous works have devised different ways to improve health care scheme, through the use of technological innovation for home health care (Chandler, 2014), (Winkley et al., 2012), (Dogali Cetin et al., 2015), (Lamonaca et al., 2015), (Rajkomar et al., 2015), (Baig et al., 2013). Developed countries, such as France and Australia, have implemented services for the remote monitoring of patients supported in information technologies (Basilakis et al., 2010). These systems report the readings of vital signs to data processing centers, where the information is used for monitoring and control of patients.

For the home health care needs, diverse works have been developed. Some focused on electronics for the collection and transmission of data (Gallego Londoño et al., 2010), (Toshiba Semiconductor & Storage Products Company, 2013), (Jiménez González et al., 2014) and others focused on their analysis and processing (Villar-Montini, 2009), (Dogali Cetin et al., 2015), (Skubic et al., 2015), (Fanucci et al., 2013), (Guevara-Valdivia et al., 2011), (Abo-Zahhad et al., 2014), (Cheng et al., 2009), (Leite et al., 2011). The studies reviewed show

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that the supply of sensors is not very wide in terms of the number of signs that can be monitored, however, there is interest and many ongoing investigations that allow inferring a tendency to increase the sensors supply. Companies such as Fitbit, iHealth Lab, MIR, Activ8rlives, OMRON, NONIN, A&D Medical, BEURER, Vitaphone, Movisens and others, have vital signs reading equipment with the ability to centralize data on their own servers. These consolidated data can be consulted subsequently by users through services provided by each manufacturer.

Although diverse technologies have been developed that integrate information from remote sensors, no work has been identified that consolidates and analyzes data from heterogeneous manufacturers. Per the above, it has been found the opportunity to build SICOBIO, a system for the consolidation and analysis of biomedical information from heterogeneous and remote devices. The system provides synchronous and asynchronous analysis. The synchronic analysis contains a fuzzy logic model that qualifies the patient's risk level based on a combination of vital signs, and generates alerts that are prioritized and delivered to the patient's caregivers. Asynchronous analysis contains statistical and segmentation models for both individual follow-up and follow-up at the patient population level. These models of analysis facilitate decision-making for medical personnel, and early discharge program managers. In addition, they keep family members and caregivers informed about the patient's health status.

To present SICOBIO, this article is distributed as follows: section two, presents related works, and section three, presents the detail of SICOBIO. First, the general overview, then the technical architecture, and then a section for the consolidation component and one for the analysis component. Section four presents the system validation. Finally, section five presents the conclusions and future work.

2 RELATED WORKS

The related works will be analyzed from the perspective of five proposed process for the remote monitoring of patients (figure 1). The first process consists in obtaining patient data that can be supplied with tools such as commercial sensors, wearables, custom sensors, and sensors installed on smartphones.

Figure 1: Processes to remotely monitoring patients.

The second is the process of data transmission, consisting of the technologies needed to send the data obtained to a processing center. Some technologies available are: GSM, 3G, 4G, WiFi, Bluetooth and ZigBee. The third process is consolidation in which formats of each manufacturer are interpreted, the data is homogenized, and each patient information is separated. The fourth process is the data analysis, in which the data becomes useful information for the different stakeholders in the care of the patient. The final process is the delivery of results obtained from the analysis of the information from the patient.

2.1 Sensors to Obtaining Biomedical Signals

There are works at both, the research (Gallego Londoño et al., 2010) and commercial level (Toshiba Semiconductor & Storage Products Company, 2013). On the commercial level, there are companies dedicated to the sale of wearable physiological sensors that can be worn as part of the dress or as accessories in the form of bracelets. These sensors measure different variables such as energy expenditure, weight, steps performed, levels of skin conductance and heart rate, among others.

With the arrival of new sensors in smartphones, practical uses for health care has been discovered, such as detection of falls, bad postures, eye problems and even respiratory problems (Lamonaca et al., 2015). Likewise, potential applications of these devices have been discovered, such as portable instruments for the visualization of vital signs obtained in remote sensors (Jiménez González et al., 2014), or as tools for the capture and transmission of data obtained by not automatic means.

2.2 Home Health Care Systems

This section presents the group of works more related to SICOBIO, and, for this reason, at the end of the section a comparative analysis of these works is presented.

2.2.1 Telemedicine Systems

They are used for the tracking and remote monitoring of patients. Some works are responsible for monitoring heart disease through the use of pacemakers or automatic defibrillator, with remote satellite surveillance (Guevara-Valdivia et al., 2011) (Villar-Montini, 2009). In those works, the patient data is transmitted to a service center where it is processed and analyzed by medical staff. From there, an order can be transmitted to the device to adjust a certain parameter (for example the heart rate) (Fanucci et al., 2013). Data transmission is done in two ways: the usual data, are transmitted in batch once a day; and unusual data, according to the system parameterization, is transmitted in near real time to ensure the timely reaction of medical staff.

As a complement to the systems of remote monitoring of patients, technologies for home monitoring has been developed (Winkley et al., 2012). These systems identify people´s behavior patterns, and over time may infer unusual behaviors for the generation of reminder, warning or danger messages (Agreda and Gonzalez, 2014).

2.2.2 Systems for Signals Analysis

These works deal with both, the collection and transmission of data, as well as their analysis and processing. In order to obtain vital signs, portable technologies are being developed to obtain data from the patient, without them being conscious (Baig et al., 2013). The data obtained by these devices are sent to a central server for processing and analysis (Dogali Cetin et al., 2015).

Due to the risk level of some patients, it is necessary to have redundant communication channels to ensure that the warning signals arrive to their receiver and guarantee an immediate reaction from medical staff to any eventuality. In this meaning, prototypes have been developed (Abo-Zahhad et al., 2014) for ECG (Electrocardiogram), SPO2 (Blood Oxygen Saturation), temperature and blood pressure sensors, which report data to a central computer for diagnosis of chronic diseases. These systems use two channels depending on the type of information they are going to transmit. For normal readings, they use the standard network. In the case of atypical readings, they use GSM / GPRS networks to transmit alert messages to emergency services and caregivers.

2.2.3 Systems for Decision Support

These systems obtain data and send it to a centralized system that maintains a knowledge base from which medical personnel can take decisions. For these systems rule engines are used in which physicians can set parameters according to the patient (Basilakis et al., 2010). When the monitoring system detects signals that exceed the configured thresholds, the system can generate alerts.

For the analysis of data, there are works that through data mining techniques, perform synchronous and asynchronous analysis. In (Chauhan et al., 2010), they apply a cluster algorithm for the analysis of databases with medical information of patients with cancer. In (Dudik et al., 2015), they illustrate a comparative analysis of some density based cluster algorithms for the analysis of patients with swallowing problems. In (Duclos-Gosselin et al., 2015), they propose data mining techniques to solve the problem of contracting nosocomial pneumonia, and in (Tomar and Agarwal, 2013), they present the utility of classification, cluster, association and regression algorithms in the health care. They propose using predictive mining techniques, to identify patients at high risk of disease, and / or to validate different treatment options.

2.2.4 Alert Generation Systems

These systems evaluate the consolidated data, and identify unusual conditions, from which generate notifications to those interested in patient care. In intra-hospital systems, they generate warning signals when monitoring instruments detect abnormal signs, and they are integrated with other systems using protocols such as HL7 (Cheng et al., 2009). The generated alerts are analyzed and qualified by healthcare professionals regarding their clinical relevance, to determine if the alert is good (Skubic et al., 2015). With these systems, it is possible to determine when a patient is stable, and ready to release the bed that can be occupied by a patient who requires it most urgently (Leite et al., 2011).

2.2.5 Comparative Analysis of Home Health Care Systems

From related works, a comparative analysis was made from the perspective of the following criteria:

Real-time transmission: Indicates whether the system has support for real-time or batch transmission. *Protocol*: Classification of protocols used by the sensor to send the obtained data. *Wearable:* Indicates whether the sensor can be part of the dress. *Monitored Signs*: Provides vital signs data monitored by the sensor.

Table 1: Comparative Systems for Remote Patient Monitoring.

Work	Real time	Protocol	Wear able	Monitored Signs	Gateway	Third-party	Analy sis
(Guevara et al., 2011)	YES, and Batch	Wireless GPRS/SMS	YES	Heart rate (Defibrillator)	CardioMessen ger (Germany)	NO	YES
(Fanucci et al., 2013)	YES, and Batch	Bluetooth/ ADSL/GSM	NO	Chronic Heart Failure (CHF)	Personal Computer	NO	YES
(Dogali Cetin et al., 2015)	YES	WiPort Ethernet	NO	Temperature / Blood pressure	Wireless Ethernet	NO	NO
(Abo-Zahhad et al., 2014)	YES, and Batch	GSM/GPRS	NO	Temperature / Blood pressure	Mobile-Care Unit	NO	YES
(Basilakis et al., 2010)	NO	Internet	NO	Chronic Obstructive Pulmonary Disease	Phone	NO	YES
(Skubic et al., 2015)	YES	Infrared	NA	Early Detection of Diseases	WSN	NO	YES
(Leite et al., 2011)	YES	SMS, Email	NA	Systolic and diastolic blood pressure.	NA	NO	YES

Gateway: Device used to obtain data from the sensor and responsible for sending it to a processing or display device. *Consolidate third-party data:* If the system is enabled to consolidate and homogenize third-party data. *System of Analysis of Information*: If it contains a server for processing and analysis of the information collected.

From the comparative work, it was possible to establish that there are gateways to proprietary technologies such as *CardioMessenger* and for opened technologies through smartphones, laptops and sensor networks. GSM/GPRS mobile communication protocols are used in critical signal tracking systems such as ECGs and pacemakers. Most works, transmit data in "near real time", and only few use wearables. Most perform analysis on the data obtained in their proprietary formats, but none consolidates data from third-party technologies, a topic that will be developed in the next chapter.

3 SICOBIO

3.1 General Outline of the Solution

Figure 2 presents the general outline of the proposed solution for monitoring patients at home. The block "*A. Means for Home Care* ", represents the patients in their home, with their different monitoring devices, and considering different protocols that can have these equipment, for the transmission of the readings to the server. Block "B. Consolidation and Analysis", is composed of interfaces that integrate third-party servers, and interfaces that directly receive signals from a gateway. These interfaces that are installed in the server must implement the functionalities of interpretation of the delivery formats and of data validation and homogenization. When the data is consolidated, the control is passed to the analysis server, in which synchronous analysis are performed for early identification of risk signs, and asynchronous analysis, over historical data of a patient, or patient set. If the system identifies a risk signal, it sends a warning signal to the group of people responsible for patient care.

3.2 Technical Architecture of SICOBIO

SICOBIO has been designed under a layered architecture (figure 3). The *obtention layer* represents the devices and components that obtain and transmit patient data. The *consolidation layer* contains the components that process the data received from the obtention component, and the *analysis layer* contains the models for analysis and alert generation.

Data collection can be achieved using wearable physiological sensors, monitoring systems, sensors on smart phones, or manually entered information. Some sensors studied send the data of the readings to proprietary servers from which they must be downloaded by an adapter that reports them to SICOBIO for consolidation and analysis.

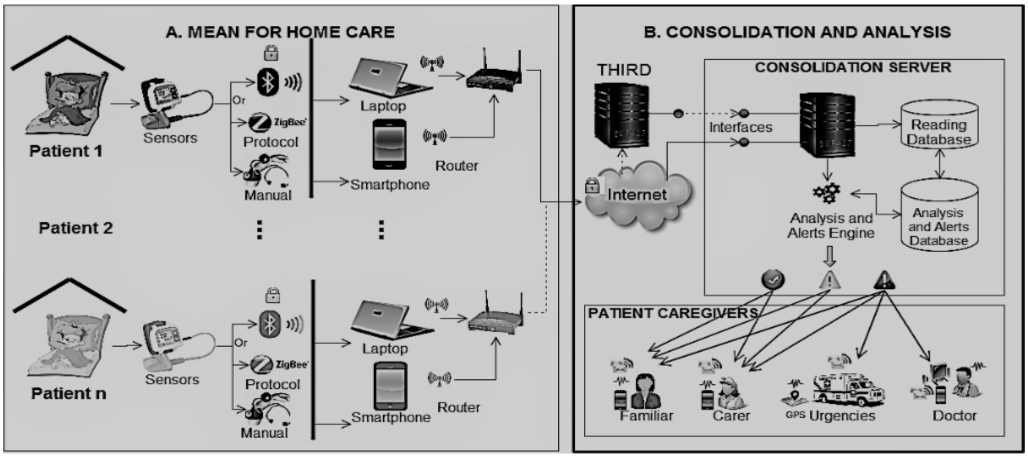

Figure 2: Outline of a Home Health Care Support Scheme.

When a new message arrives, the service passes it to a reception controller in which the source format is identified, and the appropriate structures are instantiated for its treatment. After obtaining the data or the data set, the system identifies the type of signal to which each datum belongs, and performs the tasks of homogenization and validation, to ensure that the data is in the units accepted by the system. The system persists the data in the database and sends an analysis request message to the analysis component which receives the request with the processed data and depending on the received data, it instantiates the appropriate analysis method. For example, if you receive data on systolic blood pressure and oximetry, the analysis based on fuzzy logic is instantiate to obtain a risk rating. The methods of analysis in SICOBIO, have been cataloged thus:

Synchronous analysis: identifies risk signals and generates alerts that are sent to the alert controller, which retrieves the data of those interested in receiving the notification according to the level of urgency (High, Medium, Low). It also instantiates the specialized component in the delivery of the alert and sends the alert. For a high urgency level, it uses the SMS component, for a medium urgency level, it uses the e-mail component, and for a low urgency level, the persistence component.

Asynchronous analysis: Analysis performed on historical information of a patient so that the treating physician can see the evolution of the patient regarding a given treatment and on consolidated information about several patients to help understand phenomena related to the population.

All the system configuration, such as data of patients, physicians, caregivers, equipment, units of measurement, pathologies, programs, users of the system and standardized and classified readings are found in the early discharge component (figure 3).

As follows, the components that make up each of the layers of the system and a description of their responsibilities are presented:

3.2.1 Obtention Layer

This layer is responsible for obtaining and transmitting data. Its main components are:

Native components: responsible for transmitting the data to the consolidation service in its native format. *Adapter components*: responsible for connecting to third-party servers, retrieving information from the readings of a device, and transmitting them to the consolidation service. *Manual reporting components*: responsible for the recording of readings obtained manually, and transmit them to the consolidation service.

3.2.2 Consolidation Layer

This layer is responsible for the homogenization and consolidation of data. Its main components are:
Data receiving component: Web service in charge of receiving the message. *Controller component*: Responsible for resolving the format of the message and delivering it to the appropriate component for processing. *Formats processing components*: Responsible for processing the corresponding format. *Signal processing components*: Responsible for retrieving the data of the processed format, and apply the homogenization and validation on each data reported. In homogenization, the data is passed to the unit of measure accepted by the system, and in the validation, the data is marked as normal or atypical. (Example, a SPO2 > 100, is an atypical value). *Data persistence component*:

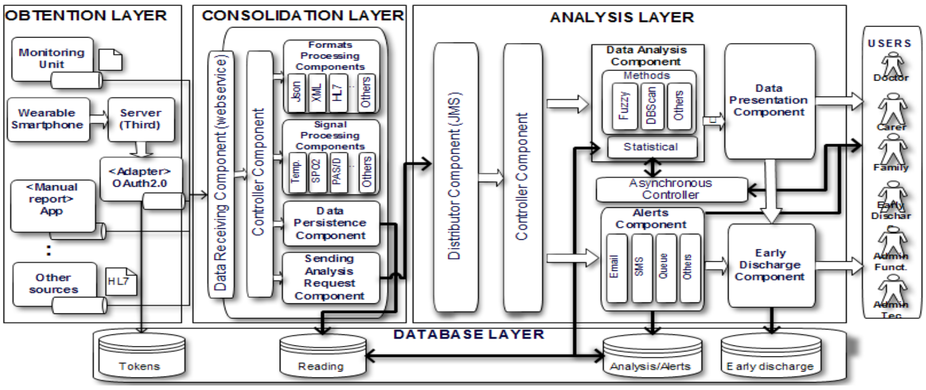

Figure 3: Architecture of SICOBIO.

Responsible for persisting the homogenized and validated data. *Sending analysis requests component*: Responsible for sending a message to the analysis component, with details of the data or set of data that has been processed.

3.2.3 Analysis Layer

Layer responsible for synchronous and asynchronous analysis, delivery of alerts and parameterization of the system. Its main components are:

Distribution component: Receives the analysis requests, and passes them to the controller component. *Controller component*: Determines the type of synchronous (light) analysis applicable to received data. *Asynchronous controller component*: Controls the processes of analysis of historical data. *Data analysis components*: It is an abstract and extensible component, responsible for performing the synchronous and asynchronous analysis, and generating the patient's risk rating. It supports decision making to medical staff and functional administrators through trend charts, scores, boxes and whiskers, point clouds, value tables and segmentation algorithms. *Alerts component*: It is an abstract and extensible component, in charge of selecting the most appropriate channel for sending the alerts per the level of risk of the patient. *Data presentation component*: Displays the result of the data analysis. *Early discharge component*: Registers early discharge processes, and maintains system configuration (doctors, caregivers, equipment, etc.).

4 VALIDATION

Validation is presented in two sections, one for the consolidation model, and the other by the analysis model.

4.1 Consolidation Model Validation

For this validation, we performed tests with three Fitbit devices that measure weight (aria), physical activity (flex), and heart rate (HR). The three devices were associated to different people, and data collection was maintained between the first and second semester of 2016.

The data was synchronized, using an adapter that takes the readings from the Fitbit server, and reports them to the consolidation component. The adapter was designed to take readings with a frequency of five minutes. This validation obtained the following results: 121 data was processed in batches, corresponding to readings taken between January 1, 2016 and April 30, 2016 through flex device. On May 2016, 30 records of daily heart rate readings were processed, taken with the HR device. A quantitative verification of the values of the physical activity data loaded for each one of the dates in the database PostgreSQL was carried out, with respect to the data that the fitbit server registered for the same dates and the difference was zero.

The validation of the second semester (from June 1 to November 7, 2016) occurred in an interval of 160 days, during which, 27 readings were obtained from the flex device, 112 readings from the HR device, and 57 readings from the aria device. These records were processed and uploaded to the database, in which they were verified and validated using the same technique used for the data of the first semester.

A second validation process was performed by capturing vital signs data from an application developed in Android. For these tests, data was entered in different units (for example: Celsius degrees, Fahrenheit degrees, Reaumur degrees, beats per minute, beats per hour), and the system correctly performed the transformations to the accepted units.

Temperature (Celsius degrees), heart rate (beats per minute). Likewise, depending on the vital sign, and its unit scale, tests were performed to prove that the system adequately marks the typical or normal data, and differentiated them from atypical data, or out of the range expected for a given unit of measure.

4.2 Analysis Model Validation

This model was validated from a technical and functional point of view. For the *technical validation*, vital sign data was sent from a smartphone. The system consolidated and sent the processed data to the analysis model in which synchronous analyses were applied for systolic blood pressure and oximetry signals. Using a fuzzy logic model, the system rated risk and generated different types of alert. The calculations performed by the system were validated against previously calculated control data, and identical results were obtained.

The *functional validation* of the analysis model was performed using the Technology Acceptance Model- TAM (Venkatesh and Bala, 2008). The Direction of Aging, the Office of Biomedical Management of the San Ignacio University Hospital and the Office of Public Health of the *Pontificia Universidad Javeriana* were involved.

The scores resulting from the validation process were rated on a scale from 1 to 7 (1-Strongly Disagree, 2-Moderately Disagree, 3-Somewhat Disagree, 4-Neutral, 5-Somewhat Agree, 6-Moderately Agree, 7-Strongly agree). The average rating was 5.7 / 7.0. The aging direction rated it at 5.7 / 7, the biomedical management office rated it at 5.9 / 7 and the public health office rated it at 5.5 / 7. The quality output item was best validated by the Direction of Aging. Likewise, the evaluations of behavioral intention and perceived utility have had a positive evaluation, which also validates the practical utility of the system.

5 CONCLUSIONS AND FUTURE WORK

According to the related works, it can be seen the interest that exists for the development of systems of remote monitoring of patients. In the short term, it is expected that a wide range of commercial and non-commercial devices will be available to obtain biomedical signals.

The SICOBIO model offers scalability for the integration of new devices, for the incorporation of new analysis algorithms, and for the integration of technologies for the delivery of alerts. Its scalability was validated through transparent incorporation of devices for the measurement of the heart rate, physical activity, and weight measurement. The architecture proposed and the technologies used for the implementation of the prototype, allow the deployment of the system in a high availability environment. Our approach is the first one including scalability in consolidation, analysis and delivery of alerts. This way, the system can evolve as the technology evolves.

As future work, it is suggested the integration of new devices, new analysis models, and new components for the delivery of alerts (e.g. Whatsapp, automatic calls) that take advantage of the scalability offered by the system design. Likewise, the exploitation of historical information through mining predictive models is suggested. It is suggested to enrich the prototype of the mobile APP so that, through the sensors installed on a smartphone, it obtains and transmits data of the patient's activity, and / or as a channel of communication between the doctor and the caregiver.

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